REMARKS

The Rejection Under 35 U.S.C. § 102

Claims 14 and 17 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Kanios et al ("Kanios") (5,719,197). Applicant respectfully traverses.

The Applicant's claims are directed to buccal spray compositions capable of transmucosal absorption of an active compound through the oral mucosa to the systemic circulatory system. The only reference in Kanios to any dosage form being applied to the oral mucosa is in the background of the art referring to a local anesthesia (Kanios, col. 1, lines 46-55) and at col. 6, lines 59-61, again referring only to a local anesthesia composition. Moreover, in both instances, Kanios fails to disclose any buccal spray composition.

The Office Action also acknowledges that "Kanios is essentially about topical application by a flexible or adhesive composition." The Applicant's claims, in contrast, recite a buccal spray composition, which is not disclosed or even suggested based on any fair reading of Kanios. The Office Action, however, points to columns 9 and 10 of Kanios and alleges:

> Kanios is teaching other forms of compositions including liquid sprays. Applicants attention is drawn to column 9, lines 19-27, where Kanios recites "For example, in ONE embodiment, the anesthetic agents are dissolved in a solvent .... and then added to an adhesive. In ANOTHER embodiment, the resulting mixture is in cream, gel..., spray solution or other non-finite composition...". Also in column 10, lines 57-65 Kanios discloses that ".... when a non-finite carrier such as an ointment, gel, lotion ... or spray-solution is used".

Applicant respectfully disagrees that these passages of Kanios can be said to disclose or suggest the claimed buccal spray. The cited passages of Kanios actually read as follows (emphasis added):

> The composition in question can then be applied to a flexible backing or a combination of backings which will serve to define the size and shape of a single dosage of the composition. Such backing may be a three dimensional material such as paper, a non-woven fabric or a natural or synthetic polymer substance. Methods of coating backings are well-known in the art and include techniques involving Mayer rod, gravure, and knife-over roll. Further processing of backings may involve the use of converting equipment for die cutting.
>
> The finished dosage form will be substantially occlusive to water permeation in in vivo.
>
> For example, in one embodiment, the anesthetic agents are dissolved in a solvent, preferably a polyhydric alcohol, and then the resulting mixture is added to an adhesive prior to being placed onto the flexible form or backing. In another embodiment, the resulting mixture is an cream gel, emulsion lotion, salve, plaster, paste, ointment, spray-solution or other "non-finite" composition. The final form which the composition of the invention will be applied depends upon the anatomical site of application and ease of access.

The finished dosage form of Kanios is made of an active agent and either a finite or non-finite pharmaceutical carrier (i.e., the "resulting mixture" in col. 9, lines 21 and 23). There is no disclosure in Kanios that the "resulting mixture" is administered directly to the oral mucosa in any form, much less as a buccal spray. According to Kanios, the composition in question is made into a "finished dosage form" by applying a flexible backing which further defines the size and shape of the finished dosage form, which is, among other things, occlusive to water permeation in vivo. In contrast to the present invention, Kanios never discloses that its finished dosage form is a spray, much less a buccal spray capable of providing a systemic effect.

At column 10, lines 57-65 (cited in the Office Action), Kanios refers to appropriate "sizes" of the composition and the amount of agent per "surface area" of the finished dosage form. That this paragraph of Kanios also refers to mg/ml concentrations for anesthetic agents is in no way a disclosure of a spray final dosage form. The intermediate resulting mixture of Kanios will have a concentration of active when added to an adhesive, backed by a flexible backing, or otherwise made into the finite finished dosage form of

Kanios. Therefore, simply because an anesthetic agent concentration is disclosed, does not disclose or suggest a finished dosage form suitable for spraying on the oral mucosa. Such a spray dosage form is never contemplated or taught by the portion of Kanios cited in the Office Action, or in any other portion of the Kanios disclosure.

In addition, the Applicant's claims require that the composition is capable of providing transmucosal absorption to the systemic circulatory system. This is not a mere intended use, but instead a required property -- i.e., the recited buccal spray composition is capable of absorption systemically through the oral mucosa. Kanios nowhere discloses this property, which is required by each of Applicant's claims, in any of the topical, locally acting, dosage forms disclosed therein. Kanios does not even remotely disclose or suggest the claimed property in any buccal spray. The principles of "inherency" cannot aid the Kanios disclosure in this regard, because Kanios never discloses any finished dosage form buccal spray and, for the disclosed dosage forms of Kanios, Kanios makes it explicit that those are topical, locally acting compositions.

There is absolutely no disclosure or suggestion in Kanios of a composition that is sprayed on the oral mucosa and/or capable of providing transmucosal absorption of the active compound through the oral mucosa of a mammal to the systemic circulatory system, as presently claimed. Kanios merely discloses local anesthetic agent compositions that are administered -- not sprayed -- topically and then have a local effect. While Kanios refers to a shotgun list of pharmaceutical agents, there is, however, no disclosure or suggestion of a buccal spray dosage form capable of providing transmucosal absorption of an active compound to the systemic circulatory system through the oral mucosa, as presently claimed.

For each of the above reasons, Applicant submits that the § 102 rejection is improper and should be withdrawn.

The Rejection Under 35 U.S.C. § 103

Claims 15-16 and 18-22 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Kanios et al (5,719,197) in view of Singer et al ("Singer") (5,364,616). Applicant respectfully traverses.

Singer refers to methods for preventing or treating gingivitis (inflammation of the gums) or periodontitis (inflammation of the tissue that support the teeth) comprising topically administering to gingival tissue of the oral cavity a composition comprising a safe and effective amount of a selective histamine-2 receptor antagonist compound (See, e.g., Singer, col. 2, lines 32-37 and col. 1, lines 16-17 and 26-27).

The Examiner cites Singer for allegedly disclosing concentration ranges and examples of flavoring agents. The mere disclosure of concentration ranges and examples of flavoring agents does not overcome the deficiencies in Kanios, i.e., that unlike the claimed invention, Kanios' finished dosage forms are not buccal sprays, much less buccal sprays capable of systemic active ingredient effect.

To treat gingivitis or peridontitis one would want the composition to remain in the oral cavity and not to be delivered to the systemic circulatory system. Indeed, Singer states that the disclosed "topical, oral carrier" denotes a composition "which is administered topically to the oral cavity, held therein for a period of time, and then is largely expectorated rather than being swallowed" (See, e.g., Singer, column 15, lines 26-30). There is no disclosure or suggestion in Singer of a buccal spray capable of transmucosal absorption to provide an active compound to the systemic circulatory system, as presently claimed.

The proper inquiry for obviousness is whether the references disclose each and every feature of the claim (See, e.g., MPEP, 1242) and whether the references suggest the invention and provide one of ordinary skill in the art with a reasonable expectation of success. In re Vaeck, 947 F.2d 488, 20 U.S.P.Q. 2d 1438 (Fed. Cir. 1991); In re

O'Farrell 853 F.2d 894, 7 U.S.P.Q. 2d 1673 (Fed. Cir. 1988). Neither Kanios nor Singer render the present claims obvious since neither of the references, either alone or in combination, (a) discloses each and every feature of the invention and (b) provides a reasonable expectation of success. There is no disclosure or suggestion in either Kanios or Singer of a buccal spray composition capable of being applied to the oral mucosa to provide an active compound to the systemic circulatory system or any disclosure on how to get a systemic effect via a buccal spray composition or method. Furthermore, neither Kanios or Singer, either individually or in combination, provides the required reasonable expectation that a composition applied to the oral mucosa could provide an active compound to the systemic circulatory system, as presently claimed.

For the above reasons, Applicant respectfully requests that the rejections under 35 U.S.C. § 103(a) be reconsidered and withdrawn.

In view of the above, Applicant believes the pending application is in condition for allowance. If the Examiner should believe that anything further may be required to place this application in even better form for allowance, she is cordially invited to telephone the Applicant's undersigned representative.

Dated: April 4, 2005

Respectfully submitted,

By _____

James W. Brady, Jr.
Registration No.: 32,115
DICKSTEIN SHAPIRO MORIN &
OSHINSKY LLP
2101 L Street NW
Washington, DC 20037-1526
(202) 785-9700
Attorney for Applicant